

REMARKS

Claims 1-44 are pending in the above-referenced application. Claims 1-6, 8, 9, 11-33, 35, 37, 38 and 42-44 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,449,532 to Storz (hereinafter “Storz”). Claims 7 and 36 are rejected under 35 U.S.C. §103(a) as being unpatentable over Storz as applied to claims 1 and 31 and further in view of U.S. Patent No. 4,862,891 to Smith (hereinafter “Smith”). Claims 10 and 39-41 are withdrawn as being drawn to a non-elected invention.

Claim 7 has been amended to correct a typographical error. Specifically, the term “taped frustaconical configuration” has been amended to “tapered frustaconical configuration”. No new matter has been added by this amendment, and support for the amendment may be found in paragraph 35 and Figure 2. Claim 14 has also been amended to correct a typographical error.

Applicants appreciate the in-person interview generously granted by the Examiner on February 18, 2009. In the interview, Applicant’s representatives argued that grooves 11 disclosed by Storz do not prevent free rotation of a tubular member; the grooves are for grasping and do not thread and connect to another tube. Claim 11 has means for language directed toward page 9 of the specification. The Examiner indicated these arguments appear persuasive. The Examiner and Applicant’s representatives also discussed if the corners of Storz were tissue engaging members formed on the exterior surface. At the close of the interview, the Examiner indicated that the 102(b) rejection would likely be withdrawn following the formal written reply to the office action.

For the following reasons, claims 1-9, 11-38 and 42-44 are believed to be in a condition for allowance.

REJECTION OF CLAIMS 1-6, 8, 9, 11-33, 35, 37, 38 AND 42-44 UNDER 35 U.S.C. §102 TO STORZ

Claims 1-6, 8, 9, 11-33, 35, 37, 38 and 42-44 are rejected under 35 U.S.C. §102(b) as being anticipated by Storz. Applicants respectfully assert that claims 1, 11, 19, 26, 31 and 42 as written possess clear novelty over Storz.

Regarding independent claim 1, the claim includes tubular first and second dilators with the limitation of, *inter alia*, “the second dilator mechanically engaging with the first dilator such that the

second dilator is forced to travel along a fixed path that prevents free rotation of the second dilator relative to the first dilator while at least a portion of the second dilator is being advanced over the first dilator”. Storz does not disclose dilators which mechanically engage such that a second dilator is forced to travel along a fixed path that prevents free rotation of the second dilator relative to a first dilator. No mechanical engagement, or any other means or ability, is shown or described, which forces a second dilator to travel along a fixed path which prevents free rotation of the second dilator relative to a first dilator. In contrast, Storz describes that a tube with a particular external diameter d_a can be fitted *with a clearance* into the opening of the following tube with diameter d_i [col. 2, lines 49—52]. No mechanical engagement between dilators causing restriction of rotation between dilators is disclosed or suggested.

Claim 11 recites, *inter alia*, “means for forcing the second dilator to travel along a substantially fixed path that prevents free rotation of second dilator relative to the first dilator while at least a portion of the second dilator is being advanced over the first dilator.” Again, Storz does not disclose any means for forcing a second dilator to travel along a substantially fixed path that prevents free rotation of the second dilator relative to a first dilator. As discussed in the interview summarized above, there is no evidence that the grooves 11 in Figure 2 force the second dilator to travel along a substantially fixed path, and/or prevent rotation of the second dilator relative to the first dilator, and indeed no evidence that grooves on one dilator could even engage with another dilator. The grooves 11 described are merely to facilitate grasping (col. 3, lines 34-36, also claim 3) and are not disclosed as providing any kind of engagement between dilators.

Claim 19 includes the limitations of: “a first mating member formed on an exterior surface of a first tubular body of a first dilator; and a second mating member being formed on an interior surface of a second tubular body of a second dilator, the second mating member engaging with the first mating member when the first dilator is received within the passageway of the second dilator.” Storz discloses no mating members formed on either first or second dilators. As presented above, the grooves 11 seen in Figure 2 are not disclosed as providing any kind of engagement between dilators. Moreover, there is no disclosure of any kind of feature or member formed on the interior surface of any dilator. No part of the specification describes a mating member formed on an interior surface of a dilator, and none of the drawings show any mating member on an interior surface.

The rejection does not point out where the limitations of claim 26 are disclosed in the prior art. Specifically, claim 26 recites “a first tissue engaging member formed on the exterior surface of the first tubular body at or toward the distal insertion end” and “a second tissue engaging member being formed on the exterior surface of the second tubular body at or toward the distal insertion end”. Indeed, Storz does not disclose any such tissue engaging members formed on the exterior surfaces of the bodies at or toward the distal end, or in fact anywhere. The grooves 11 seen in Figure 2 are not disclosed as tissue engaging members, and moreover they are clearly not located at toward the distal end, but are instead located “at the proximal end” [col. 2, line 63, and claim 3].

The ends of the tubes are also not tissue engaging members as they are clearly defined in the specification. MPEP 2111.01(I) sets forth that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. *In re Zletz*, 893 F.2d 319,321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989; *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004). The specification states in paragraph [066] that “The present invention also provides tissue engaging members. The tissue engaging members enable smooth and controlled advancement of the dilators into the body tissue.” The end 14 of the tube 4 is a right angle, and as such would not enable smooth and controlled advancement of the dilators into the body tissue.

Claim 31 recites a dilator with an elongated tubular body, and, *inter alia*, “a first mating member formed on the interior surface of the tubular body”. As set forth previously with regard to claim 19, Storz does not disclose any kind of member formed on, or otherwise located at, an interior surface of a tubular body. The grooves seen in Figure 1 and Figure 2 are not shown as being formed on or at an interior surface; if they were they would be indicated by dotted lines, similar to the dotted lines which indicate the inner wall of the tube.

Finally, claim 42 recites a method for dilated bodily tissue which includes “advancing the second dilator over the first dilator such that through at least a portion of the advancement, the second dilator mechanically engages with the first dilator so as to prevent free rotation of the second dilator around the first dilator”. For the same reasons as set forth previously with regard to claim 1, Storz does not disclose or suggest mechanical engagement between dilators so as to prevent free rotation of a second dilator.

Since the prior art reference does not disclose all the limitations of claims 1, 11, 19, 26, 31 and 42, these claim are not anticipated by the reference. Claims 2-6, 8 and 9 depend from claim 1 and are therefore not anticipated for the same reasons as for claim 1. Claims 12-18 depend from claim 11 and are therefore not anticipated for the same reasons as for claim 11. Claims 20-25 depend from claim 19 and are therefore not anticipated for the same reasons as for claim 19. Claims 27-30 depend from claim 26 and are therefore not anticipated for the same reasons as for claim 26. Claims 32-35, 37 and 38 depend from claim 31 and are therefore not anticipated for the same reasons as for claim 31. Claims 43 and 44 depend from claim 42 and are therefore not anticipated for the same reasons as for claim 42. Withdrawal of the rejection is respectfully requested.

REJECTION OF CLAIMS 7 AND 36 UNDER 35 U.S.C. §103 OVER STORZ IN VIEW OF SMITH

Claims 7 and 36 are rejected under 35 U.S.C. §103(a) as being unpatentable over Storz in view of Smith. Regarding both independent claims 1 and 31, the rejection sets forth that Storz teaches the claimed invention but does not specify the geometry of the dilator. However, as set forth above regarding the 102(b) rejection, Storz does not disclose all the limitations recited in independent claims 1 and 31, specifically “the second dilator mechanically engaging with the first dilator such that the second dilator is forced to travel along a fixed path that prevents free rotation of the second dilator relative to the first dilator” in claim 1, and “a first mating member formed on the interior surface of the tubular body” in claim 31. Smith also does not disclose these limitations, so the combination of Storz and Smith does not teach all the limitations of the independent claims from which claims 7 and 36 depend. Therefore claims 7 and 36 are patentable over the cited combination for at least the reasons set forth above. Withdrawal of the rejection is respectfully requested.

CONCLUSION

Claims 1-9, 11-38 and 42-44 are believed to be in condition for allowance. If there are any remaining issues preventing mailing of a Notice of Allowance, the Examiner is respectfully requested to contact the undersigned.

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Respectfully submitted,

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